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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/849,686	08/21/1997	ARNE HELGE DEGGERDAL	08269/003001	4163

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EXAMINER

OWENS JR, HOWARD V

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 07/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/849,686

Applicant(s)

DEGGERDAL ET AL.

Examiner

Howard V Owens

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,5-17,19-25 and 27-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-17,19-25 and 27-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 28,30.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **Detailed Action**

The following is in response to the election filed 2/24/03:

An action on the merits of claims 1, 5-15, 17, 19-24 and 27, 28 and 30 is contained herein below.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

### **Response to Restriction Requirement**

Applicant's election with traverse of Group I in Paper No 31. is acknowledged. The traversal is on the ground(s) that Group I contains dependent claims drawn to the use of magnetic beads in the separation of nucleic acids which would encompass the search required for Group II. As such, claims 1, 5-17, 19-25, 27-34 will be examined on the merits.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-8, 10-14, 17, 24, 25, 27 and 30-34 rejected under 35 U.S.C. § 102(b) as being anticipated by Hawkins, U.S. Patent No. 5,898,071.

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Claims 1, 14, 15, 28 and 31-34 are drawn to a method of isolating genomic DNA from a sample comprising contacting said sample with a detergent and a solid support in the absence of any chaotropic agent, whereby soluble genomic DNA is bound to the support in a sequence-independent manner and separating said support with bound genomic DNA from the sample.

Dependent claims 5-10 limit the detergent composition.

Dependent claims 11-13 limit the solid support to particulate magnetic beads.

Dependent claims 16, 27, and 30 are drawn to kits containing the compositions/methodology set forth in claims 1 and 28.

Hawkins teaches a method of isolating DNA acid from a sample in the absence of any chaotropic agent via binding of the nucleic acid to a magnetic polymer bead in the presence of the detergent SDS composition (columns 4-9). Hawkins also teaches that although the temperature is not critical, the temperature may be elevated to meet separation conditions of the DNA (col. 7, lines 12-15). Hawkins also teaches the subsequent separation of the sample from the bound support through wash steps with a buffer; packaging of this process in a kit (columns 8-9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1, 5-17, 19-25 and 27-34 are rejected under 35 U.S.C. § 103 as being unpatentable over Hawkins, U.S. Patent No. 5,898,071.

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Claims 1, 14, 15, 28 and 31-34 are drawn to a method of isolating genomic DNA from a sample comprising contacting said sample with a detergent and a solid support in the absence of any chaotropic agent, whereby soluble genomic DNA is bound to the support in a sequence-independent manner and separating said support with bound genomic DNA from the sample.

Dependent claims 5-10 limit the detergent composition.

Dependent claims 11-13 limit the solid support to particulate magnetic beads.

Dependent claims 16, 27, and 30 are drawn to kits containing the compositions/methodology set forth in claims 1 and 28.

Claim 29 is drawn to a kit for isolating RNA and genomic DNA from a sample comprising superparamagnetic polystyrene beads; oligo dT beads and one or more detergents.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

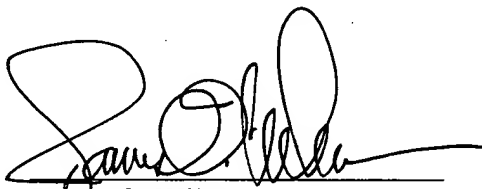
Hawkins teaches a method of isolating DNA acid from a sample in the absence of any chaotropic agent via binding of the nucleic acid to a magnetic polymer bead in the presence of the detergent SDS (columns 4-9) wherein the use of magnetic beads obviates the need for centrifugation. Hawkins also teaches the subsequent separation of the sample from the bound support through wash steps with a buffer; as well as the packaging of this process in a kit (columns 8-9). Hawkins does not teach the use of oligo dT beads in the DNA separation composition; however, the use of oligo dT beads to bind RNA as an adjunct method in nucleic acid separation was commonly known in the art (see applicant's admission on p. 3, last paragraph). When applicant states that something is prior art, it is taken as being available as prior art against the claims. Admitted prior art can be used in obviousness rejections. In re Nomiya, 509 F.2d 566, 184 USPQ 607, \*611 (CCPA 1975)

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It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made

A person of ordinary skill in the art would have been motivated to separate genomic DNA from RNA using a magnetic particle given the prior art's teaching that fast and efficient removal of DNA is afforded from nucleic acid samples via the use of functionalized magnetic particles.

Howard V. Owens  
Patent Examiner  
Art Unit 1623



James O. Wilson  
Supervisory Patent Examiner  
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (703) 308-4624 . The fax phone number for this Group is (703) 308-4556.